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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,335	01/30/2004	Sanyog M. Pendharkar	ETH-5084 NON PROV	6518

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EXAMINER

DESAI, ANAND U

ART UNIT PAPER NUMBER

1653

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/768,335	Applicant(s) PENDHARKAR ET AL.	
	Examiner Anand U. Desai, Ph.D.	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 20-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-19 in the reply filed on September 12, 2005 is acknowledged.

Priority

2. The priority date is January 30, 2004.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on January 30, 2004 is being considered by the examiner.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7, 12, and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 7 recites the limitation "said particle". There is insufficient antecedent basis for this limitation in the claim.

7. Claim 12 recites the limitation "said gas". There is insufficient antecedent basis for this limitation in the claim. Suggest, "said biocompatible gas".

8. Claims 17, and 18 recite the limitation "said composition". There is insufficient antecedent basis for this limitation in the claim. Suggest, "said hemostatic composition".

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9. Claim 19 recites the limitation "said functional additive". There is insufficient antecedent basis for this limitation in the claim. Suggest, "said additive".

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Pendharkar et al. (US 2005/0037088 A1).

Pendharkar et al. disclose a sterilized hemostatic composition comprising biocompatible liquid, solid (polymer), and gas phases as its three necessary components (see paragraph [0011]). "The composition comprise a continuous liquid phase in which the solid particles and gaseous phase are substantially homogenously dispersed." (see paragraph [0020]). "Any biocompatible gas may be used to prepare compositions of the present invention, including, but not limited to air, carbon dioxide, nitrogen, xenon, or argon." (see paragraph [0021]). "The solid particles, liquid phase, and gaseous phase generally will be present in compositions made by processes of the present invention at a ratio of from about 1:2:1 to about 1:12:13, based on weight:volume:volume (g:ml:ml)... The density of compositions of the present invention will be from about 0.9 g/ml to about 0.3 g/ml." (see paragraph [0022]). "The hemostatic compositions may further comprise effective amounts of one or more additives... Glycerol may be present in

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the compositions up to about 20% by weight, ...based on the weight of the liquid phase. In addition, quaternary amines may be used to provide enhanced properties to the compositions. For example, benzalkonium chloride, Polybrene or Onamer M may be used at levels up to about 1 percent by weight, based on the weight of the liquid phase. In certain embodiments benzalkonium chloride is used at levels of from about 0.001% to about 0.01%, ...based on the weight of the liquid phase. It is believed that the quaternary amines may serve multiple functions, acting as an antimicrobial agent, a foaming agent, a radical scavenger and/or as a heparin neutralizer.” (see paragraph [0024]). The hemostatic composition may further comprise thrombin and fibrinogen (see paragraph [0025], and Examples, particularly 9, and claim 18).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

12. Claims 1, 12, 13, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Spillert et al. (US 2003/0129183 A1).

Spillert et al. disclose “a hemostatic composition, which comprises at least one procoagulant metal ion and at least one procoagulant biopolymer... The procoagulant biopolymer may be, for example, one or **more** of the following: **collagen**, **thrombin**, prothrombin, fibrin, **fibrinogen**, heparinase, Factor VIIa, Factor VIII, Factor IXa, Factor Xa, Factor XII, von

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Willebrand Factor, a selectin, a procoagulant venom, a plasminogen activator inhibitor, glycoprotein IIb-IIIa, proteases, or plasma.” (see paragraphs [0007], [0028], and claim 1). “The hemostatic composition of the invention may also include a carrier, such as, but not limited to, polyethylene glycol, hyaluronic acid, cellulose, oxidized cellulose, methyl cellulose, or albumin. These may be used to provide a matrix, a **suitable viscosity**, deliverability, adherence, or other properties desired to be imparted to the compositions herein for easy in application to a wound. Numerous other carrier which impart these characteristics are embraced herein.” (see paragraph [0036], and claim 10). “The hemostatic composition of the invention may be in the form of, for example, a paste, dough, glue, liquid, lyophilized powder or **foam**, for application to a wound.” (see paragraphs [0008], and [0037], and claim 12). Foam is defined in Merriam-Webster dictionary as, a material in a lightweight cellular form resulting from introduction of gas bubbles during manufacture. The composition is administered to treat bleeding and would therefore necessarily be sterile. The composition disclosed by Spillert et al. discloses the hemostatic composition currently being claimed (current application, claims 1, 12, 13, 17-19).

Conclusion

13. No claims are allowed.

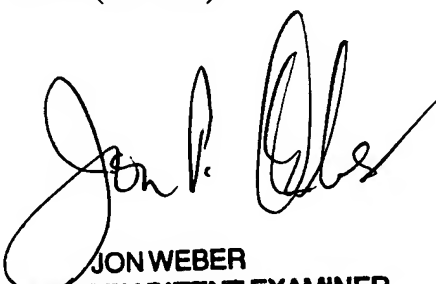
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 14, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER